

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

CAROLYN BARNHILL,

Plaintiff,

vs.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

8:20-CV-182

MEMORANDUM AND ORDER

I. INTRODUCTION

This matter is before the Court on Carolyn Barnhill’s motion to exclude certain opinion testimony of Dr. Roger Goldberg. [Filing 45](#). This is a products-liability, personal-injury case arising from Barnhill being implanted with a surgical mesh manufactured by Boston Scientific Corporation (“BSC”). Dr. Goldberg is a physician retained as an expert witness by BSC for this litigation. The Court will partially grant and partially deny Barnhill’s motion for the reasons stated herein.

II. BACKGROUND

This case comes before the Court following transfer from the multi-district litigation panel at docket number 2326. [Filing 52-6](#). The case was part of the seventh wave of cases to be transferred to various district courts for final disposition. [Filing 52-6](#).

Plaintiff, Carolyn Barnhill, alleges in June 2010, she was implanted with an Advantage Fit system manufactured by Defendant, BSC, to treat her stress urinary incontinence. [Filing 12 at 5](#). She further alleges that because of the implantation of this device she “experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures . . . and other

damages.” [Filing 52-4 at 16](#). Barnhill brings numerous products-liability, personal-injury claims against BSC. [Filing 1 at 4-5](#). BSC denies liability for Barnhill’s injuries. [Filing 52-5 at 8-12](#).

Prior to this case’s transfer to this Court, the MDL judge, the Honorable Joseph R. Goodwin, set deadlines concerning disclosure of experts in pre-trial order number 208 (“PTO 208”). [Filing 11](#). PTO 208 also set forth how the parties were to file *Daubert* motions. [Filing 11 at 5-6](#). Judge Goodwin directed the parties to file “*Daubert* motions on general causation issues only,” in the MDL; specific causation motions in the individual cases; and where an expert was both general and specific, the parties were to file a general causation motion in the MDL and a specific causation motion in the individual case. [Filing 11 at 5-6](#).

BSC disclosed Dr. Goldberg as one of its retained expert witnesses and provided Barnhill with a Rule 26 report detailing his opinions. [Filing 45-1](#). Barnhill now challenges the admissibility of Dr. Goldberg’s disclosed opinions relating to the adequacy of BSC’s product warnings and the complication rates he observed in his own practice. [Filing 46 at 1](#). The parties also dispute whether Dr. Goldberg’s challenged opinions address general causation, and if so, whether they can be challenged by means of the present motion or whether such challenge should have been filed in the MDL in accordance with PTO 208. [Filing 48 at 11-12](#); [Filing 50 at 6-7](#).

III. DISCUSSION

Barnhill moves to exclude two of Dr. Goldberg’s opinions proffered in his Rule 26 expert report ([Filing 45-1](#)). [Filing 45](#). BSC opposes Barnhill’s motion in all respects. [Filing 48](#). As an initial matter, the parties also dispute whether this motion is properly before this Court, with BSC arguing the challenged opinions are general in nature and thus should have been challenged in the MDL and not here the individual case. [Filing 48 at 11-12](#); see also [Filing 50 at 6-7](#) (disputing the general nature of the opinions). The Court will first address this dispute. The Court will then

consider each challenged opinion in turn. Ultimately, the Court partially grants and partially denies Barnhill's motion.

A. Legal Standard

Under Federal Rule of Evidence 702, expert opinion testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue," it is "based upon sufficient facts or data," and it is "the product of reliable principles and methods" which have been reliably applied "to the facts of the case." *Fed. R. Evid. 702*. The court must be mindful that expert opinions "can be both powerful and quite misleading." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595, 113 S. Ct. 2786, 2798, 125 L. Ed. 2d 469 (1993). In considering admissibility, the district court's job as gatekeeper is to "ensure that all scientific testimony is both reliable and relevant." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006) (citing *Daubert*, 509 U.S. at 580, 113 S. Ct. at 2790, 125 L. Ed. 2d). The inquiry "is a flexible one designed to 'make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Id.* (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 1176, 143 L. Ed. 2d 238 (1999)). "Courts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *Id.* at 758. However, "[e]xpert testimony is inadmissible if it is speculative, unsupported by sufficient facts, or contrary to the facts of the case." *In re Wholesome Grocery Prods. Antitrust Litig.*, 946 F.3d 995, 1001 (8th Cir. 2019) (citing *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000)).

"A district court has great latitude in determining whether expert testimony meets the reliability requisites of Rule 702." *Craftsmen Limousine, Inc. v. Ford Motor Co.*, 363 F.3d 761, 776 (8th Cir. 2004). To meet the reliability requirement, the proponent of an expert opinion must

show “that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid.” *Marmo*, 457 F.3d at 757-58; *see also Daubert*, 509 U.S. at 592-93, 113 S. Ct. at 2796, 125 L. Ed. 2d (stating that the court must assess “whether the reasoning or methodology underlying [an expert opinion] is scientifically valid”). “[C]onclusions and methodology are not entirely distinct from one another.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 519, 139 L. Ed. 2d 508 (1997). “When the analytical gap between the data and proffered opinion is too great, the opinion must be excluded.” *Marmo*, 457 F.3d at 758.

To satisfy the relevance requirement, the proponent of an expert opinion must demonstrate “that the reasoning or methodology in question is applied properly to the facts in issue.” *Id.* A court is not required to “admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Joiner*, 522 U.S. at 146, 118 S. Ct. at 519, 139 L. Ed. 2d. In exercising its gatekeeping role under *Daubert*, the court must focus “specifically on the methodology.” *Synergistics, Inc. v. Hurst*, 477 F.3d 949, 955 (8th Cir. 2007).

B. The Effect of PTO 208

Before reaching the admissibility of Dr. Goldberg’s opinions, the Court must address the parties’ dispute over whether the present motion is the proper vehicle to challenge them. BSC argues that because Dr. Goldberg’s report contains both general and specific opinions and the challenged opinions address general causation, Barnhill was required by PTO 208 to file her challenge in the MDL and not here in the individual case. Filing 48 at 11-12. Barnhill argues that Dr. Goldberg’s report was case-specific, and the challenged opinions directly relate to specific causation and are thus subject to challenge here. Filing 50 at 6-7. To address this issue, the Court looks first to Judge Goodwin’s order regarding expert discovery, PTO 208.

In PTO 208, Judge Goodwin set the deadline for MDL defendants' expert disclosures for September 18, 2019. [Filing 11 at 3](#). The parties were to file *Daubert* motions no later than November 4, 2019. [Filing 11 at 3](#). "For the filing of *Daubert* motions on general causation issues only, the parties [were] instructed to file one *Daubert* motion per expert in the main MDL (MDL 2326) instead of the individual member case." [Filing 11 at 5](#). Specific-causation *Daubert* motions were to be filed in the individual member cases. [Filing 11 at 6](#). In the case of an expert that was "both a general and specific causation expert," the parties were to "file a general causation motion in the main MDL 2326 and an individual specific causation motion in an individual member case." [Filing 11 at 6](#). Thus, if Dr. Goldberg was properly disclosed as both a general and specific expert, Barnhill's challenge to any general-causation opinions should have been made before the MDL court. However, if Dr. Goldberg was only disclosed as a specific-causation expert, Barnhill can rightly challenge any of his opinions here.

As Barnhill notes, [Filing 50 at 6-7](#), the expert report containing the opinions she challenges in this motion is specific to her case. Compare [Filing 45-1 at 1](#) (Goldberg's report at issue, denoting Barnhill as its subject), with [Filing 52-24 at 21](#) (Goldberg's general report, denoting "General Opinions of the Uphold Device" as its subject). However, PTO 208 made the proper channel for presenting *Daubert* motions contingent on whether the expert was disclosed as "both a general and specific causation expert," and not whether the challenged opinion appeared in a case-specific or general report. [Filing 52-6](#) at 5-6. Here, Dr. Goldberg was properly disclosed as both general and specific expert. In fact, Barnhill adopted a motion challenging the admissibility of some of the opinions proffered in his general-expert report in this litigation. [Filing 52-28](#) ("Notice of Adoption of Prior Daubert Motion of Dr. Roger Golberg for Wave 7 Cases"); see also [Filing 52-24 at 21](#) (Dr. Goldberg's general report as an exhibit in Plaintiff's motion to exclude). PTO 208 is clear that

to the extent the challenged opinions embrace matters of general causation, Barnhill should have addressed them in her *Daubert* motion before the MDL court, and not here in the individual case.

C. The Challenged Opinions

Barnhill challenges the admissibility of Dr. Goldberg's opinions regarding the adequacy of the Advantage Fit's directions for use ("DFU") and the complication rates among patients in his own practice. [Filing 46 at 1](#).

1. Opinion that the DFU Was Adequate and Did Not Need Additional Warnings

Barnhill challenges the admissibility of Dr. Goldberg's opinion that the Advantage Fit DFU "was adequate and did not need to contain additional warnings." [Filing 46 at 4](#). She argues Dr. Goldberg lacks expertise in product-warning labels, which renders him unqualified to opine on the DFU's adequacy. [Filing 46 at 4](#). BSC argues that Dr. Goldberg's training and experience as a urogynecologist qualify him to consider the injuries Barnhill complained of and the warnings presented in the DFU, compare them, and opine as to whether the DFU adequately warned of the injuries suffered. [Filing 48 at 5](#).

The Court agrees that "[an experienced physician] need not be an expert on product warnings per se" to evaluate a product warning within their field of medical expertise. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D.W. Va. 2014). Further, as BSC characterizes Dr. Goldberg's work comparing the DFU's warnings with the injuries Barnhill complains of, there is no question a matter of specific causation is presented. See [Filing 48 at 5](#). Dr. Goldberg's methodology (comparing the DFU's warnings and the injuries identified in Barnhill's medical records) is scientifically valid. The Court finds that Dr. Goldberg is qualified to opine as to whether the DFU adequately warned of the injuries Barnhill alleged and therefore denies Barnhill's motion in this respect.

However, to the extent BSC contends that Dr. Goldberg may opine that the DFU warned of “all potential complications,” and does not need additional warnings, the Court concludes that Dr. Goldberg should not be allowed to provide such opinions. See [Filing 48 at 7](#) (quoting [Filing 45-1 at 19](#)).

This is not the first time an issue relating to Dr. Goldberg’s opinion on the adequacy of a DFU has arisen in this litigation. See [Filing 52-27 at 10](#). The MDL court has already determined the unreliability of Dr. Goldberg’s causation opinions regarding the adequacy of warnings related to a similar mesh-based device used for treating pelvic organ prolapse. [Filing 52-27 at 10](#) (excluding Dr. Goldberg’s opinion regarding whether additional warnings should be included in the DFU for the Uphold device, as his experience as a physician did not provide a reliable basis for such opinions). In *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 584 (S.D.W. Va. 2014), the MDL court excluded an expert physician’s potential testimony that a warning was adequate because the expert had not previously witnessed unwarned-of complications. The court found this was not a reliable basis for the expert’s opinion. *Id.* Here, Dr. Goldberg similarly presents no reliable basis for his opinion that the DFU “adequately warns of all potential complications.” [Filing 45-1 at 19](#).¹

The Court finds that Dr. Goldberg may opine on the adequacy of the DFU with respect to Barnhill and her injuries specifically, but he may not opine on the DFU’s adequacy in general, nor

¹ BSC appropriately argues that challenges to a general- and specific-causation expert’s general-causation opinions should have been made in the MDL pursuant to PTO 208. [Filing 48 at 11-12](#). Although Dr. Goldberg’s proposed opinion that the DFU warned of “all potential complications” is arguably one of general causation, the Court concludes there are distinguishing factors that allow the Court to exclude this opinion here. First, Dr. Goldberg was disclosed as a general-causation expert in this case, and Dr. Goldberg’s same opinion being addressed here was excluded in the MDL with regard to another mesh device. [Filing 52-27 at 10](#). BSC is not prejudiced by exclusion now because BSC has already had full opportunity to argue for inclusion of this opinion with regard to a similar device in the MDL. Finally, the Court concludes that in this circumstance, even if a challenge to this particular opinion should have been made in the MDL, the Court’s gatekeeping function under *Daubert* and its progeny requires the Court to exclude this opinion in this particular situation even if the objection was untimely.

that it “adequately warns of all potential complications.” *See Filing 45-1 at 19*. The Court partially grants and partially denies Plaintiff’s motion to exclude the testimony accordingly.

2. Opinion of the Complication Rates for Dr. Goldberg’s Patients

Next, Barnhill challenges the reliability of Dr. Goldberg’s opinion that, “[i]n his own 20 year career, [he has] implanted thousands of midurethral slings and [has] observed remarkably high rates of success with essentially no serious complications, and an impressively low rate of minor complications such as vaginal mesh exposure or need for revision.” *Filing 46 at 5* (quoting *Filing 45-1 at 6*). Barnhill alleges this opinion is “devoid of any factual support.” *Filing 46 at 5*. BSC counters that Dr. Goldberg’s statement is not an opinion, but a factual summary. *Filing 48 at 9*. Further, BSC points out that Dr. Goldberg, in his next sentence, continues that his own clinical experience and an “extensive number of published studies” have led him to his conclusions regarding the safety and efficacy of mid-urethral slings. *Filing 48 at 9-10* (quoting *Filing 45-1 at 6*). The Court denies Barnhill’s motion on this point both because such a general opinion should have been challenged in the MDL, *see Filing 11* at 6, and because Dr. Goldberg’s opinion is both reliable and relevant, *see Marmo, 457 F.3d at 757* (The district court must “ensure that all scientific testimony is both reliable and relevant.”).

The Court first notes that Dr. Goldberg’s statement relates to the propensity of the product to cause harm to patients as a community, and therefore, it is a general-causation opinion. *See Junk, 628 F.3d at 450*. Thus, Barnhill should have taken her opportunity to challenge it in the main MDL in accordance with PTO 208. Although the Court could determine this opinion to be admissible due to Barnhill’s failure to challenge the general opinion in the MDL alone, upon review of the opinion, the Court concludes the opinion is admissible regardless of the timeliness of Barnhill’s challenge.

The Court acknowledges that Dr. Goldberg's statement necessarily includes some elements of opinion; what is a "remarkably high rate[] of success" to one might be low to another. *See Filing 45-1 at 6.* However, the Court, like BSC, reads this statement in the context of his full report as setting forth part of Dr. Goldberg's basis for his ultimate general-causation opinion on the safety and efficacy of mid-urethral slings. An expert can observe a "low" rate of complication and "high" rate of success in his practice without conducting a full scientific study to determine the precise rates of occurrence involved; this is a different case than that in which an expert opines as to specific complication rates based on nothing more than memory and estimates. *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 (S.D.W. Va Sept. 1, 2016) (excluding expert testimony about personal complication rates where the expert estimated specific rates with no clear method). An experienced clinician is entitled to rely in part on his experience, especially while also pointing to studies that support the conclusions his clinical experience leads him towards. *See Tyree*, 54 F. Supp. 3d at 585 (finding a physician's opinion that a device is safe and effective is reliable where it was based on his clinical experience and review of scientific literature). Further, an experienced physician's estimates of high success and low complication rates, with nothing more said, are not inherently unreliable or irrelevant when offered as a partial basis for an opinion on a medical device's safety. Accordingly, the Court denies Barnhill's motion on this point.

IV. CONCLUSION

For the foregoing reasons, Barnhill's Motion in Limine is partially granted and partially denied. The following of Dr. Goldberg's potential opinion testimony will be excluded:

- any opinions that the Advantage Fit DFU adequately warns of all potential complications or does not require any further warnings;

The following of Dr. Goldberg's potential opinion testimony will be allowed:

- the DFU adequately warned of Barnhill's injuries; and
- in his own practice, Dr. Goldberg "observed remarkably high rates of success with essentially no serious complications, and an impressively low rate of minor complications such as vaginal mesh exposure or need for revision."

IT IS ORDERED:

1. Plaintiff's Motion in Limine ([Filing 45](#)) is partially granted and partially denied as set forth above.

Dated this 9th day of October, 2020.

BY THE COURT:



Brian C. Buescher
United States District Judge